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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,956	07/14/2001	Avi Ashkenazi	10466/66	4189

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1649

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/904,956

Applicant(s)

ASHKENAZI ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-46 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-46 and 49-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Formal matters***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

### ***Response to Amendment***

2. Claims 42-44 have been amended as requested in the amendment filed on July 07, 2005. Following the amendment, claims 42-46 and 49-51 are pending in the instant application.

Claims 42-46 and 49-51 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on July 07, 2005 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Objections***

6. Claims 42-43 stand objected to because of the following informalities: claims 42-43 depend from cancelled claim 39, see reasons of record in section 6 of Paper mailed on January 13, 2005. Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

7. Claims 42-46 and 49-51 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in previous communication from the office.

At pages 4-6 of the Response, Applicant discusses issues related to legal standards of utility rejections and refers to the Utility Examination Guidelines. Applicant argues that “a utility is “specific” when it is particular to the subject matter claimed” and refers to *Nelson v. Bowler* to support a statement regarding “specific” therapeutic use”. Applicant also cites *Cross v. Iizuka* and submits that *in vitro* results are sufficient to support practical asserted *in vivo* utility. Applicant further discusses what constitutes “a substantial utility” with respect to the interpretation of the phrase “immediate benefit to the public” (see page 7 of the Response). Applicant’s arguments have been carefully considered but are not persuasive for the reasons that follow.

Applicant asserts the utility of the claimed polypeptides comprising SEQ ID NO: 91 (PRO266 polypeptides) as “useful to prevent tumor invasiveness, and/or possibly, to destroy tumor cells” based on the positive experimental data obtained in the skin vascular permeability assay as disclosed in Example 77. As fully explained in the previous office actions of record, based on the information presented in the instant specification, as filed, one skilled in the art would reasonably conclude that the disclosed PRO266 polypeptides could represent a novel proinflammatory molecule. However, since the instant specification fails to provide any evidence or sound scientific reasoning that would allow a conclusion that this instant alleged proinflammatory polypeptide of SEQ ID NO: 91 is useful in treating any particular form of

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cancer, or is capable of destroying tumor cells, or to treat any or all of autoimmune diseases, Applicant's asserted utility for the polypeptide of SEQ ID NO: 91 constitutes a utility that requires further research to identify or reasonably confirm a "real world" context of use (see *Brenner v. Manson*). This type of utility is not considered a "substantial utility". While disclosure of a polypeptide that has a stated correlation to a specific disease condition would be considered a "specific and substantial" utility in the context of identifying potential candidates for clinical or preventive measures, in the instant case the polypeptide is suitable only for additional research.

Applicant's arguments that "[t]he discovery of PRO266 as a proinflammatory molecule provides for the first time the ability to exploit this target as a therapeutic agent for treating [invasive cancers or autoimmune diseases]" are not persuasive particularly in view of the absence of information of the biological activity of PRO266 polypeptides or the type of cancer or autoimmune disease to be treated. The art clearly recognizes that class of proinflammatory molecules is characterized by broad range of activities (see reasons of record in the previous office action, for example). Therefore, in order to use PRO266 polypeptides "as therapeutic target to prepare anti-inflammatory agents", for example (bottom at page 10 of the Response), a skilled practitioner would have to first perform a substantial amount of further research to establish its practical utility by discovering the biological role of PRO266 with respect to a particular disease or condition.

The Examiner maintains that because the instant specification does not disclose a credible "real world" use for the claimed polypeptides, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

***Claim Rejections - 35 USC § 112***

8. Claims 42-46 and 49-51 stand rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

***New grounds of rejection necessitated by amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 42-46 and 49-51, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 42-44, as amended, are vague and ambiguous because the relationship between the plurality of elements recited therein is not clear. Specifically, the claims are directed to an isolated polypeptide having identity to or comprising (a); (b); (c). The structure of the claimed polypeptide is not obvious and cannot be determined from the claims. Applicant is advised that recitation of (a); (b); or (c) would obviate this ground of rejection.

11. Claims 45-46 and 49-51 are indefinite for being dependent from indefinite claims.

*Conclusion*

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

August 22, 2005